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### 510K SUMMARY

**Owner:** Gallini s.r.l.  
88/90 Via S. Faustino  
41037-Mirandola-Italy

**Contact:** Paul L. Hawthorne  
U.S. Representative  
C/O Coeurage Enterprises  
3106 Bretton Court  
Glen Allen, VA 23060

**Submission Date:** April, 1996

**Device Name:** Speed-Cut® - Automatic Biopsy System

**Predicate Device:** ACECUT Automatic Biopsy System  
Meadox Medical, Inc.

**Description of Device Function:** The Speed-Cut® is an automatic spring loaded, depth programmable, disposable biopsy instrument.

**Intended Use:** An automatic biopsy system designed to take core samples from a variety of soft tissues, including (but not limited to) liver, prostate, kidney.

### TECHNOLOGICAL CHARACTERISTICS

The SPEED-CUT® Automatic Biopsy System is equivalent to the predicate device in terms of technological characteristics.

Due to the variety of sizes available for this device, it may be used in laparoscopic procedures. The small size and longer needles facilitate placement through one of the incisions while the surgeon "views" the tissue to be biopsied using fiber optics or ultra-sound.

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The following tests were performed to verify the safety and efficacy of the instrument.

TEST	RESULTS
Firing Test*	Passed
Intracutaneous Reactivity	Passed
Acute Systemic Activity	Passed
Pyrogen Test	Passed
Cytotoxicity	Passed

\* - Gallini exhaustive test procedures (firing until failure) indicate the Speed-Cut® biopsy instruments may be fired on average fifty (50) times before failing. The manufacturer feels a ten to one (fire to fail/max.pt. use)ratio provides adequate safety margin.